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| 09/758,308 | 01/10/2001 | Howard A. Fields | 14114.0349U2 | 9952 |

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| EXAMINER |
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LI, BAO Q

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| ART UNIT | PAPER NUMBER |
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1648

DATE MAILED: 11/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/758,308

Applicant(s)

FIELDS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-25 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4-6,9,11-16,18-23 and 32-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 10, 17, 24-25 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-6, 9-25 and 27-40 are pending.

Election/Restrictions

1. Applicant's election with traverse of group II, in the scope of NS3 protein and its corresponding sequence in Paper No. 19 is acknowledged. The traversal is on the ground(s) that examiner has not shown that it would be a serious burden to search and examine all claims, especially a serious burden for searching all groups together for the second requirement of restriction requirement. Further, Applicants amend claim 3 and request claim 3 to rejoin with elected group II.
2. Upon considering the previous precaution history, group II in the scope of HCV core and NS3 and their corresponding sequences of SEQ ID NO: 1 and 2 are considered. Claim 3 is rejoined with elected group II.
3. Claims 3, 9-10, 16-17, 24, 25 and 40 are considered before the examiner.
4. However, other claims 11-15, which are not read on the cope of HCV core and NS3 are not considered because they required different searches and constitute a serious burden for the office. For example, the search for SEQ ID NO: 2 or 1, do not need to search of SEQ ID NO: 3-5. Therefore, they are withdrawn from the consideration alone with other non-elected claims 1,2, 4-6, 23, 32-39. The restriction is proper and then made Final.

RCE

5. A request paper No. 17, filed on 05/22/2003 for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/22/2003 has been entered. An Office Action on RCE follows:

Response to Amendment

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6. The amendment, paper No. 13, filed 06/23/01 has been acknowledged. Claims 7-8 and 26-31 are canceled. Claims 9-13 are amended. New Claims 32-40 are added. Claims 1-6, 9-25 and 32-40 are pending before the examiner.

7. Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Matter rejection of claim 7

8. The rejection is moot in view of the cancellation of the claim 7.

Claim Rejections - 35 USC § 112

9. The rejection on claims 7 and 26 on the second paragraph is moot in view of the cancellation of the claims 7 and 26.

Claim Rejections - 35 USC § 102

10. The rejection on claims 7 and 26 under **35 USC § 102** (b) over Chien et al. (a) is moot in view of the cancellation of the claims 7 and 26.

Claim Rejections - 35 USC § 103

11. The rejection on claims 7 and 26-31 under **35 USC § 103** (a) over Chien et al. (a) and Kato et al. is moot in view of the cancellation of the claims 7 and 26-31.

12. Regarding claims 9-12, the rejection is moot in view new ground of rejection.

New Matter Objection

13. The amendment filed Feb 19, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure as new matter, is as follows: “ wherein the mosaic polypeptide is not the HCV polypeptide” in line 3 of claims 9-10 and lines 3 to 4 of claim 40.

14. Applicant is required to cancel the new matter in the reply to this Office Action.

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New Ground of Rejections:

New Matter Rejection

15. Claims 9-10 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the amendment “ wherein the mosaic polypeptide is not the HCV polypeptide” in line 3 of claims 9-10 and lines 3 to 4 of claim 40 filed on 02/19/2003, paper No. 13, are new matter, which are not disclosed in specification as it was original filed.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Jin et al. (Arch. Biochem. Biophys. 1995, Vol. 323, No. 1, pp. 47-53).

18. Jin et al. disclose a recombinant HCV NS3 comprising amino acid residues 1207-1612 with a polyhistidin tag. Because the rejected claims use an open language “comprising” to describe the claimed mosaic polypeptide, Office interprets the claimed polypeptide broadly as any polypeptide having the amino acid residues of NS3 amino acid residues 1470-1573, but not only containing amino acid residues 1470-1573, in combination with any other non-NS3 sequence (See lines 54 on col. 5 to line 23 on col. 7). Therefore, the claimed invention is anticipated by the cited reference.

19. For the basis of this rejection, Applicants’ attention is directed to MPEP regarding the transitional term “comprising” used in the claim language:

20. The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be

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Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

21. If Applicants wish to claim the mosaic polypeptide only contains an epitope from the particular region of NS3 exclusively, please amend the claims to use more precise language for describing the structure of the mosaic polypeptide. Otherwise, the claimed invention is anticipated by the cited prior art.

22. Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Yagi et al. (Biol. Pharm. Bull. 1996, Vol. 19, No. 10, pp. 1254-1260).

23. Yagi et al. disclose a chimeric HCV antigenic polypeptide named CepCM comprising more than one of HC antigenic epitopes from NS3 and other structural and non-structural antigenic protein fragments including core and NS4. Yagi et al. further teach to use the polypeptide for doing immunoassay after coating the micro-well plates with CepCM polypeptide antigen to detect the anti-HCV antibodies in biological specimens from HCV infected patients (See lines 39 on 1st col. of page 1257 through 20 on 2nd col. of page 1258, especially, tables 3 and 4). They found that CepCM contains some NS3 epitopes and NS4 epitopes (See line 5 on 1st col. of page 1258 to line 4 on 2nd col. of page 1258). Therefore, the claimed invention is anticipated by the cited reference.

24. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Houghton et al. (US Patent NO. 5,683,846A).

25. Houghton et al. disclose a combination antigenic polypeptide comprising HCV core (1-120 amino acid residue, and two additional HCV antigens selected from group consisting of NS3 from amino acid residues of 1050-1640, HCV NS4 from amino acid residues 1640-2000 and HCV NS5 from amino acid residues 2000-3011). The antigenic polypeptide taught by Houghton et al. contains sequence exogenous to HCV and is expressed as a recombinant fusion protein (See line 1-35 on col. 5). Furthermore, they teach that an immunoassay by using

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recombinant antigenic polypeptide comprising HCV core and NS3 to detect HCV antibodies in a biological sample (See lines 11 on col. 6 through 23 on col. 7). Because the rejected claims use an open language “comprising” to describe the claimed mosaic polypeptide, Office interprets the claim 10 broadly as any polypeptide having the amino acid residues of NS3 amino acid residues 1470-1573, but not only containing amino acid residues 1470-1573, in combination with any other non-NS3 sequence (See lines 54 on col. 5 to line 23 on col. 7). Therefore, the HCV polypeptide disclosed by Houghton et al.

26. For the basis of this rejection, Applicants’ attention is directed to MPEP regarding the transitional term “comprising” used in the claim language:

27. The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”).

28. If Applicants wish to claim the mosaic polypeptide only contains an epitope from the particular regions of HCV core and NS3, please amend the claims to use more precise language for describing the structure of the mosaic polypeptide. Otherwise, the claimed invention is anticipated by the cited prior art.

29. Claims 14-15 are rejected under 35 U.S.C. 102(b) as anticipated by Barrera et al. *Vox Sang* 1995, Vol. 68, pp. 15-18).

30. Barrera et al. disclose HCV ELISA.3 assay that incorporates a NS5 antigen in addition to the recombinant HCV antigens core, NS3 and NS4 for detecting the HCV antibodies in the clinical specimens (See entire document, especially, sections of Materials and Methods on page 15-16). Therefore, the claimed invention is anticipated by the cited reference.

31. Claims 9-10 and 24-25 are rejected under 35 U.S.C. 102(b) as anticipated by Okayma et al. (EP 464 287A1).

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677th, 333rd to 6371, or 333rd to 9362nd. The vaccine composition further comprises at least one pharmaceutical acceptable carrier (Claims 4, 6 and 21-23). While Okayma et al. is silent for the limitation of an antigenic epitope(s), the polypeptide disclosed by them inherently encodes these HCV core and NS3-NS5 regions including the epitopes (See lines 41-47 on page 9). Therefore, the claimed invention is anticipated by the cited reference.

33. For the basis of this rejection, Applicants' attention is directed to MPEP regarding the transitional term "comprising" used in the claim language:

34. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

35. If Applicants wish to claim the mosaic polypeptide only contains an epitope from HCV core and NS3-NS5 regions within particular amino acid residues, please amend the claims to use more precise language for describing the structure of the mosaic polypeptide. Otherwise, the claimed invention is anticipated by the cited prior art.

Claims 3, 16-17 and 40 are deemed free of prior art, given failure of the prior art to teach or reasonably suggest a mosaic polypeptide particularly comprising an amino acid residues 1471-1573 of HCV NS3 of SEQ NO: 2 or amino acid 1-120 of SEQ ID NO: 1 (Claims 3, 17 and 40) or an immunogenic composition comprising a mosaic polypeptide comprising one of more antigenic epitopes of HCV core, NS3 protein, NS4 protein and NS5a protein with a pharmaceutical carrier. However, claims 3 and 17 are not in the condition for allowance because they are dependent on the rejected claims 10 and 14. Claim 40 is rejected under *35 USC § 112* for the new matter issue.

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they are dependent on the rejected claims 10 and 14. Claim 40 is rejected under *35 USC § 112* for the new matter issue.

Conclusion

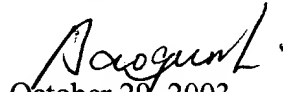
No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li


October 29, 2003